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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,956	07/14/2003	Sharat Singh	121.01US	4092
33603	7590	12/15/2006	EXAMINER	
MONOGRAM BIOSCIENCES 345 OYSTER POINT BLVD SOUTH SAN FRANCISCO, CA 94080			BARKER, MICHAEL P	
			ART UNIT	PAPER NUMBER
			1626	

DATE MAILED: 12/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/618,956

Applicant(s)

SINGH ET AL.

Examiner

Michael P. Barker

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-56 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 23, and 34 is/are rejected.
- 7) ☒ Claim(s) 2, 3, 9, 18, 24, 26, 28, 29, 39 and 41 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>2/26/04</u> . | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

**Claims 1-56** are pending. The nonelected subject matter of **Claims 1-3, 9, 18, 23, 24, 26, 28, 29, 34, 39, and 41** (in part), as well as **Claims 4-8, 10-17, 19-22, 25, 27, 30-33, 35-38, 40, and 42-56** are withdrawn from further consideration. **Claim 1** is rejected. Claims objected to are **2, 3, 9, 18, 24, 26, 28, 29, 39, and 41**.

#### *Information Disclosure Statement*

The information disclosure statement (IDS) submitted on February 26, 2004 was correctly filed. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the IDS was considered by the Examiner. Please refer to Applicant's copy of PTO-1449, submitted herewith.

#### *Response to Restriction Requirement*

Applicant's election *without traverse* of Group I, **Claims 1-22**, in the reply filed on September 26, 2006 is acknowledged, as is the election of species, Pro28-amide, depicted in the Drawings at p. 13 of 17.

As stated in the restriction requirement, the Office will review the claims and disclosure to determine the scope of the independent invention encompassing the elected compound and examination will then proceed on the elected compound and the entire scope of the invention encompassing the elected compound as defined by common classification.

The restriction requirement is withdrawn as to **Claims 23-33 and 34-44**. These claims are rejoined.

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### *Examination*

#### Elected Species

The elected species, Pro28-amide, was found to be free of the prior art. Therefore, the scope of the search was expanded as described, *infra*. The prior art search was not extended unnecessarily to cover all nonelected species.

#### Scope of Prior Art Examined

The following is the scope of the elected invention. Compounds represented by the general formula,  $G-(L-E)_m$ , wherein:

$G-(L-E)_m$  is:

- *Pro28-amide*,
- *Pro29-amide*,
- *Pro33-amide*,
- *Pro34-amide*,
- *Pro35-amide*, and
- *Pro36-amide*

including that subject matter of the following claims which reads upon these species:

- **Claims 2, 3, 9, 18, 23, 24, 26, 28, 29, 34, 39, and 41.**

The remaining subject matter of **Claim 1, 2, 3, 9, 18, 23, 24, 26, 28, 29, 34, 39, and 41** not falling into the scope of compounds set forth above, as well as claims which do not read upon the elected subject matter: **4-8, 10-17, 19-22, 25, 27, 30-33, 35-38, 40, and 42-56** is nonelected subject matter and withdrawn from consideration. The scope of the elected subject matter outlines a group of commonly classified compounds. There is no patentable coaction between the elected and nonelected subject matter. A reference anticipating one member of the

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elected subject matter will not render the nonelected subject matter obvious. Therefore, the elected subject matter is distinct from the nonelected subject matter.

The elected and nonelected subject matter is directed to art recognized as divergent, requiring different search strategies for each. Because of the Markush language, the number of permutations and combinations make it impossible to determine the full scope and complete meaning of the claimed subject matter. The burden to search the entirety of **Claim 1** is unduly burdensome. Thus, the restriction requirement set forth June 26, 2006 is deemed proper and made final.

***Claim Rejections - 35 USC § 112, ¶1***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

**Claim 1** is rejected under 35 U.S.C. 112, ¶1, because the Specification, while being enabling for at least Pro28-amide, Pro29-amide, Pro33-amide, Pro34-amide, Pro35-amide, and Pro36-amide, including that subject matter of the following claims which reads upon these species: **Claims 2, 3, 9, 18, 24, 26, 28, 29, 39, and 41**, does not reasonably provide enablement for the entirety of **Claim 1**. The following reasoning also applies to reject independent **Claims 23 and 34**. The Specification does not enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with this claim.

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Many factors are considered when determining whether the evidence is sufficient to satisfy the enablement requirement and whether any necessary experimentation is “undue.”

In re Wands, 858 F.2d 731, 742 (Fed. Cir. 1988).

These factors include, but are not limited to:

- The breadth of the claims;
- The nature of the invention;
- The state of the prior art;
- The level of one of ordinary skill;
- The level of predictability in the art;
- The amount of direction provided by the inventor;
- The existence of working examples; and
- The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

*Id.* at 738.

The breadth of the claims and nature of the invention:

**Claim 1** claims a “compound of formula:  $G-(L-E)_m$  wherein: **G** is a lipophilic moiety capable of incorporating into a lipid membrane; **L** is a cleavable linker; **E** is an electrophoretic tag; and **m** is an integer greater than 1 and less than 100.” **Claims 2, 3, 9, 18, 23, 24, 26, 28, 29, 34, 39, and 41** narrow **Claim 1** by limiting the definitions of **G**, **L**, and **E**.

**Claim 1** encompasses compounds in which **G** can be any and lipophilic moiety capable of incorporating into a lipid membrane, **L** can be any cleavable linker, and **E** can be any electrophoretic tag.

The level of one of ordinary skill in and the state and predictability of the prior art:

The level of ordinary skill in the art is extremely high, with many working in the biological and pharmaceutical sciences possessing advanced degrees. Despite the high level of ordinary skill prevalent in pharmacology, Applicant's Specification does not enable **Claim 1**.

Also, the predictability of the pharmaceutical sciences is regarded as high. Compounds with similar structures are expected to react similarly in similar environments. However, each **G**, each **L**, and each **E** do not necessarily have the same structural characteristics, depending on the chosen **G**, **L**, and **E**. Furthermore, due to structural differences among **G**, **L**, and **E**, combinations of the three moieties also cannot be expected to react similarly. The disclosure does not support the use of any **G**, any **L**, and any **E**. The state and predictability of the prior art do not suggest every combination of **G**, **L**, and **E** would react similarly in similar environments.

The amount of direction provided by the inventor and existence of working examples:

Applicant provides six working examples of species reading upon the genus of **Claim 1**. However, the evidence is specifically directed toward the use of one type of **G**, one type of **E**, and three types of **L**, including the cleavable linker depicted in **Claim 23**. The direction and working examples provided do not support making and using the claimed compounds in the method depicted in **Claim 1**.

The quantity of experimentation needed to make or use the invention based on the disclosure:

The level of experimentation necessary to make and use the claimed compounds is undue. Every type of lipophilic moiety, cleavable linker, and electrophoretic tag would need to

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be determined. Subsequently, each combination of structurally similar compounds would need to be examined. Based on the evidence provided, one of skill in the art cannot make and use all of the compounds encompassed by **Claim 1**.

### ***Objections***

**Claims 1-3, 9, 18, 24, 26, 28, 29, 39, and 41** are objected to for being dependent on rejected base claims.

### **Allowable Subject Matter**

The following subject matter is allowable:

Compounds represented by the general formula, **G-(L-E)<sub>m</sub>**, wherein:

**G-(L-E)<sub>m</sub>** is:

- *Pro28-amide*,
- *Pro29-amide*,
- *Pro33-amide*,
- *Pro34-amide*,
- *Pro35-amide*, and
- *Pro36-amide*

including that subject matter of the following claims which reads upon these species:

**Claims 2, 3, 9, 18, 23, 24, 26, 28, 29, 34, 39, and 41**. Amendments to the claims canceling all nonelected subject matter will immediately put this application in condition for allowance. Such



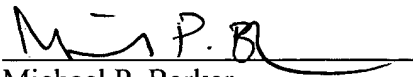
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a cancellation does not prejudice Applicant's right to file divisional applications on the nonelected subject matter.

***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael P. Barker whose telephone number is (571) 272-4341. The examiner can normally be reached on Monday-Friday 8:00 AM- 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (571) 272-0699. The unofficial fax phone for this group are (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is viable through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Michael P. Barker  
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REBECCA ANDERSON  
PATENT EXAMINER

\_\_\_\_\_  
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Continuation of Disposition of Claims: Claims withdrawn from consideration are 1-3, 9, 18, 23, 24, 26, 28, 29, 34, 39, and 41 (in part); 4-8, 10-17, 19-22, 25, 27, 30-33, 35-38, 40, and 42-56.